IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WYETH, Plaintiff, v. IMPAX LABORATORIES, INC., Defendant.	Civil Action No.: 06-222 JJF **PUBLIC VERSION**

PLAINTIFF WYETH'S MEMORANDUM IN OPPOSITION TO DEFENDANT'S MOTION TO COMPEL PRODUCTION OF DOCUMENTS IN RESPONSE TO DEFENDANT'S FOURTH SET OF REQUESTS FOR PRODUCTION

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I. NATURE AND STAGE OF THE PROCEEDINGS

This case is about Impax's attempt to obtain FDA approval to sell generic copies of Wyeth's Effexor® XR products prior to the expiration of Wyeth's patents that cover both Effexor XR and Impax's proposed products. [Complaint, D.I. 1]. Effexor XR is Wyeth's highly successful extended release formulation of venlafaxine hydrochloride, used in the treatment of major depressive disorder, generalized anxiety disorder, social anxiety disorder, and panic disorder.

Discovery began on June 23, 2006, but Impax did not serve its Fourth Set of Requests for Production of Documents and Things (Nos. 125-131) (the "Document Requests") on Wyeth until February 27, 2007. Those Document Requests sought, for the first time, sensitive documents on a future Wyeth product for which Wyeth has filed a separate New Drug Application ("NDA") with the FDA, desvenlafaxine succinate ("ODV succinate").[1] The patents-in-suit do not relate to ODV succinate, and ODV succinate is not relevant to any claims or defenses in this case. Wyeth thus objected to Impax's Document Requests on several grounds, including relevance and undue burden. After meeting and conferring on the issue, Impax filed this motion to compel production of documents (the "Motion") (D.I. 139). This is Wyeth's answering brief in opposition to the Motion.

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[1] For the sake of brevity, Wyeth will use the terms "Effexor" and "Effexor XR" to refer to its immediate release and extended release formulations of venlafaxine hydrochloride (a pharmaceutically acceptable salt of venlafaxine), respectively. Similarly, Wyeth will use the term "ODV succinate" to refer to the succinate salt of desvenlafaxine and Pristiq®, Wyeth's future product containing desvenlafaxine succinate.

II. SUMMARY OF THE ARGUMENT

The Motion seeks to compel production of documents responsive to Defendant's Fourth Set of Requests for Production (Nos. 125-131), which seeks documents comparing Effexor XR, Wyeth's commercial embodiment of the patents-in-suit, and ODV succinate, the active pharmaceutical agent in a future product under development. ODV succinate is an entirely different chemical entity than venlafaxine hydrochloride.

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The patents-in-suit do not mention ODV succinate or comparisons between Effexor XR and ODV succinate. Nevertheless, Impax argues that such comparisons are relevant to the issues of "patent validity, inequitable conduct, and commercial success." [Impax's Br., D.I. 140 at 1]. Impax theorizes that such a comparison somehow bears on the "diminished incidence(s) of nausea and emesis" referred to in the patents-in-suit. [*Id.*]. Impax omits, however, that the "diminished incidence(s) of nausea and emesis" to which the patents-in-suit refer is relative to that experienced with the *immediate release form of venlafaxine hydrochloride, Effexor*, not relative to *ODV succinate*. Impax does not and cannot dispute this point.

Consequently, Impax never explains how comparisons of Effexor XR with *ODV succinate* bear on the question of whether Effexor XR (which contains venlafaxine hydrochloride, not ODV succinate) produces less nausea and emesis relative to *immediate release Effexor* (which also contains venlafaxine hydrochloride, not ODV succinate). The references in the patents-in-suit have nothing to do with ODV succinate or comparisons of nausea and emesis in patients receiving Effexor XR and ODV succinate. Therefore, documents

comparing the nausea and emesis profiles of Effexor XR and ODV succinate simply are not relevant.

Equally irrelevant are Wyeth's future marketing plans for its future ODV succinate product. Impax says it needs these documents to challenge whether there is a nexus between the success of Effexor XR and the merits of the claimed inventions. [Impax's Br., D.I. 140 at 10-11]. But future marketing plans for a product that has yet to be launched are completely irrelevant to whether the last ten years of sales of Effexor XR were a result of the merits of the claimed inventions.

Furthermore, the scope of Impax's Document Requests is overly broad and unduly burdensome. ODV succinate was the result of a wholly independent research and development project of sweeping scope, as was the development of venlafaxine hydrochloride. The document production effort that led to the production of over a million pages of documents pertaining to formulation research and development, testing, regulatory approval, and marketing of venlafaxine hydrochloride was a massive effort that spanned over a year. To locate, identify, review, and redact (as is necessary, *inter alia*, under HIPAA) the requested documents would be a huge undertaking. Such an effort, however, is simply not warranted given the lack of relevance of the documents Impax seeks.

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III. STATEMENT OF FACTS

A. The Patent Claims At Issue

Wyeth filed this suit after Impax filed ANDA with the FDA to obtain approval for the commercial manufacture, use, and sale of Venlafaxine HCl Extended-Release Capsules. Under 35 U.S.C. § 271(e)(2)(A), this was an act of infringement of the patents-in-suit. Wyeth contends that Impax infringes claims 20-25 of U.S. Patent No. 6,274,171 ("the '171 patent"), claims 1-6 of U.S. Patent No. 6,419,958, and claims 1, 2, 13 and 14 of U.S. Patent 6,043,120, which relate to the once-daily, oral administration of an extended release formulation of venlafaxine hydrochloride that provides a specific pharmacokinetic profile and therapeutic efficacy. Claim 20 of the '171 patent is representative of the asserted claims, all of which are method claims:

> 20. A method for providing a therapeutic blood plasma concentration of venlafaxine over a twenty four hour period *with diminished incidences of nausea and emesis* which comprises administering orally to a patient in need thereof, an encapsulated, extended release formulation that provides a peak blood plasma level of venlafaxine in from about four to about eight hours, said formulation containing venlafaxine hydrochloride as the active ingredient.

[Matterer Decl., Ex. A (emphasis added)].[2]

All of the method claims are expressly limited to extended release formulations of venlafaxine hydrochloride. They do not extend to formulations of desvenlafaxine (or its

[2] "Matterer Decl., Ex." refers to the Exhibits to the Declaration of Mary B. Matterer in Support of Defendant Impax Laboratories, Inc.'s Motion to Compel Production of Documents in Response to Defendant's Fourth Set of Requests for Production (Nos. 125-131), filed on April 10, 2007. (D.I. 141).

succinate salt). There is no dispute that the claim term "with diminished incidences of nausea and emesis" refers to a comparison between the claimed extended release formulations of venlafaxine hydrochloride and immediate release venlafaxine hydrochloride. None of the asserted claims recite or invoke any comparisons between venlafaxine hydrochloride and ODV succinate. ODV succinate is not even mentioned in the patents-in-suit.

B. Wyeth's Development Of ODV Succinate

Wyeth discovered and developed venlafaxine hydrochloride, the first of a class of antidepressants (known as Serotonin Norepinephrine Reuptake Inhibitors ("SNRIs")) that was approved by the FDA. Originally sold as an immediate release formulation, Effexor® did not achieve widespread commercial success, despite the remarkable antidepressant properties of venlafaxine hydrochloride, in large part because of the need for multiple daily dosing and the nausea and emesis problems associated with the drug. The development of the once-a-day extended release formulation of the same drug unexpectedly reduced the nausea and vomiting problems that had been associated with the immediate release formulation, and led to widespread use and astounding commercial success. In short, the extended release formulation unlocked the potential of this remarkable drug, venlafaxine, and provided relief to an untold number of patients suffering from psychiatric disorders, including depression.

Sadly, not all patients respond to Effexor XR; indeed, no single antidepressant works for all patients and some patients do not respond to any of the currently available antidepressants. This leaves a large number of patients still suffering from depression. As discussed in the article attached as Ex. B to Impax's Brief, entitled "Companies Desperately Seek Antidepressant Breakthrough:"

> For those with depressive disorders, the reality of medication therapy alone is all too bleak. Research has shown that only about

> one-third of patients achieve symptomatic remission with the first antidepressant medication they try.
>
> Even after trying two antidepressants, patients with depression still have only about a 50 percent chance of achieving remission . . . .
>
> Clearly, new treatment options are needed for patients with depressive or anxiety disorders. During 2004, the most recent year for which statistics are available, an estimated 21 million people were diagnosed with major depressive disorder in the United States, Western Europe, and Japan . . ., yet only half of all patients receive any treatment.

[Matterer Decl., Ex. B at 1].

As a leader in neuroscience pharmaceuticals, Wyeth, not surprisingly, continually performs research and development in an effort to provide new pharmaceutical products to ameliorate the debilitating effects of psychiatric disorders. Wyeth's proposed ODV succinate product represents its latest efforts and continued commitment to developing therapies to help improve the lives of patients suffering from mental health disorders.

Desvenlafaxine, also a SNRI, is one of several metabolites of venlafaxine. A succinate salt form of desvenlafaxine is the active ingredient in Wyeth's new product, and is a completely different drug than venlafaxine hydrochloride, the active ingredient in Effexor XR. Its chemical structure is different, its physical properties are different, and its pharmacokinetic and pharmacodynamic properties are different.

Wyeth submitted to the FDA a NDA for ODV succinate for the treatment of major depressive disorder on December 22, 2005. The FDA issued an approvable letter on January 23, 2007 for this indication.[3] Wyeth also has filed a NDA for the use of ODV succinate

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[3] Impax states that "[t]here is no dispute that Wyeth has received FDA approval to market desvenlafaxine to treat depression." [Impax Br., D.I. 140 at 3]. An approvable letter, however, does not constitute final FDA approval to market the drug in the United States. ODV succinate is not yet on the market.

to treat vasomotor symptoms ("VMS") associated with menopause and expects an FDA action letter in the second quarter of 2007. If approved, ODV succinate will be the first and only non-hormonal medicine for the treatment of VMS associated with menopause.

Significantly, the patents-in-suit neither claim ODV succinate in any formulation nor compare ODV succinate to venlafaxine hydrochloride. Because comparisons between Effexor XR and ODV succinate have no bearing on the issues in this suit, Wyeth objected to producing such documents in response to Impax's Document Requests. [*See* Matterer Decl., Ex. G]. Wyeth's counsel met and conferred with Impax's counsel, explaining that such requests are not relevant to any issue pending in the lawsuit, but sought to understand Impax's basis for seeking such documents. Impax, however, was unable to articulate why comparisons of Effexor XR to ODV succinate purportedly are relevant. [*See* Matterer Decl., Ex. I (Letter from Robert A. Pollock to Eric L. Lane dated April 3, 2007)].

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IV. ARGUMENT

A. Scope of Discovery

Federal Rule of Civil Procedure 26(b)(1) provides that parties may obtain discovery of matters "relevant to the claim or defense of any party," or "reasonably calculated to lead to the discovery of admissible evidence." Although this rule allows for a broad scope of discovery, the Supreme Court has instructed that courts should "firmly" enforce the relevancy requirement. *See Herbert v. Lando*, 441 U.S. 153, 177 (1979) ("the requirement of Rule 26(b)(1) that the material sought in discovery be 'relevant' should be firmly applied, and the district

courts should not neglect their power to restrict discovery where 'justice requires [protection for] a party or person from annoyance, embarrassment, oppression, or undue burden or expense . . . .' Rule 26(c). With this authority at hand, judges should not hesitate to exercise appropriate control over the discovery process."); *see also Crawford-El v. Britton*, 523 U.S. 574, 598 (1998) ("Rule 26 vests the trial judge with broad discretion to tailor discovery narrowly and to dictate the sequence of discovery."). In addition, to prove relevancy, a party seeking discovery must show more than just a speculative theory that information *might* be relevant to a claim or a defense. *See Micro Motion, Inc. v. Kane Steel Co.*, 894 F.2d 1318, 1327-28 (Fed. Cir. 1990) ("A litigant may not engage in merely speculative inquiries in the guise of relevant discovery.").

Furthermore, district courts have discretion to limit or deny discovery when the information sought is overly broad or would be unduly burdensome to produce. Fed. R. Civ. P. 26(b)(2). The scope of discovery is thus limited by not only relevance but also burden. *See Surles v. Greyhound Lines, Inc.*, 474 F.3d 288, 305 (6th Cir. 2007).

B. The Documents Impax Seeks Are Not Relevant To Any Of The Claims Or Defenses In This Suit

Impax's Document Requests seek documents relating to comparisons of Effexor XR to ODV succinate. [*See* Impax Br., D.I. 140 at 4-5]. These documents are not relevant to any of the claims or defenses in this action. In patent cases, it is appropriate to limit discovery requests seeking information on products not at issue in the case. *See Funai Elec. Co. v. Orion Elec. Co.*, 2002 WL 1808419, at *4-5, *7 (S.D.N.Y. Aug. 7, 2002) (denying a motion to compel the patentee to produce documents relating to overly broad requests that sought information relating to technology and products not at issue and agreeing with patentee's "narrowing of the requests to include information within the scope of the claims"); *see also Fenster Family Patent Holdings, Inc. v. Seimens Medical Solutions USA Inc.*, 2005 U.S. Dist. LEXIS 20788, at *17-18

(D. Del. Sept. 20, 2005) (denying accused infringer's motion to compel production of documents relating to a future product still under development and outside the scope of discovery). So should the Court draw the line here, and deny Impax's motion to seek information on a future product that has no bearing on any issue in this litigation.[4]

1. The Discovery Impax Seeks Is Not Relevant To The Validity Of The Patents-In-Suit

Impax argues that the fact that certain claims in the patents-in-suit contain the language "diminished incidences of nausea and emesis" somehow makes studies comparing nausea and emesis between patients receiving Effexor XR and ODV succinate relevant to the validity of the patents-in-suit, as they would "necessarily include nausea and emesis data that may show the claimed formulation does not reduce those side effects, rendering the invention inoperative." [Impax Br., D.I. 140 at 8]. However, the patents-in-suit refer to diminished incidences of nausea and emesis for the claimed extended release venlafaxine hydrochloride formulations in comparison to conventional immediate release tablet formulations of venlafaxine hydrochloride, which are administered more than once per day. [*See, e.g.*, Matterer Decl., Ex. A ('171 patent), at col. 2, ll. 46-62]. The patents-in-suit and prosecution histories do not make any representations comparing nausea and emesis between venlafaxine hydrochloride and ODV

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[4] The only two cases cited by Impax on the scope of permissible discovery, *Pettingill v. Caldwell*, 2006 U.S. Dist. LEXIS 58651 (D. Del. Aug. 21, 2006) and *Jurimex Kommerz Transit GMBH v. Case Corp.*, 2005 U.S. Dist. LEXIS 2827 (D. Del. Feb. 18, 2005) [Impax Br., D.I. 140 at 7], have no bearing on the facts presented here. In *Pettingill*, the Court determined that a communication did not fall within the protection of the attorney-client privilege or work product doctrine; relevance did not appear to be disputed. *Pettingill*, 2006 U.S. Dist. LEXIS 58651 at *4. In *Jurimex*, the Court merely ordered the defendant to produce for deposition one or more corporate witnesses that satisfy the requirements of Fed. R. Civ. P. 30(b)(6). *Jurimex*, 2005 U.S. Dist. LEXIS 2827 at *8-9. Neither case addressed the question of whether information pertaining to a product that is not at issue in the litigation is relevant to any issue in a patent infringement case.

succinate. Comparisons of nausea and emesis between patients receiving Effexor XR and those receiving ODV succinate are not in controversy, and such comparisons are not relevant to the operability or the validity of the patents-in-suit. *See Funai Electric*, 2002 WL 1808419 at *3 (denying discovery where "Orion has failed to explain how the technical aspects of current Funai products that are not related to any claim in this case are relevant."); *id.* at *5-6 (same).

Moreover, to the extent Impax seeks information as to whether venlafaxine hydrochloride "actually achieves" diminished incidences of nausea and emesis (*see* Impax Br., D.I. 140 at 8), Wyeth offered to produce Effexor XR nausea and emesis results obtained in ODV succinate clinical trials containing an Effexor XR arm. Impax could compare that data to the data already produced to Impax relating to nausea and emesis experienced with Effexor XR as well as with the immediate release venlafaxine hydrochloride product. Impax has no need for ODV succinate comparative data to assess whether the claimed extended release formulations of venlafaxine hydrochloride diminish the incidence of nausea and emesis relative to immediate release venlafaxine hydrochloride.

2. The Discovery Impax Seeks Is Not Relevant To Inequitable Conduct

Impax's argument that the discovery it seeks is relevant to inequitable conduct makes no sense because Wyeth made no representations to the Patent Office concerning nausea and emesis of Effexor XR as compared to ODV succinate. The only comparison Wyeth made was between Effexor XR and immediate release venlafaxine hydrochloride. The Document Requests at issue do not seek documents relating to this comparison between the claimed invention and immediate release venlafaxine. They instead specifically seek comparisons between Effexor XR and ODV succinate. [*See* Impax Br., D.I. 140 at 4-5]. Therefore, such comparisons will not help Impax "determine whether Wyeth accurately represented the information regarding nausea and emesis rates to the Patent Office."

Impax further argues that: "To determine whether Wyeth accurately represented the information regarding nausea and emesis rates to the Patent Office, and whether the studies themselves accurately represent the side effect profile of Effexor XR®, Impax needs access to Effexor XR® nausea and emesis data." [Impax Br., D.I. 140 at 9]. By volunteering to produce the Effexor XR data contained in ODV succinate clinical study reports, Wyeth has offered to produce exactly the data Impax says it needs. Information pertaining to ODV succinate is completely irrelevant.

3. The Discovery Impax Seeks Is Not Relevant To Commercial Success

Impax argues that the marketing documents it seeks in its Document Request Nos. 128, 129, and 131 are relevant to its counter-argument that the commercial success of Effexor XR "is due to advertising and promotional messages and unclaimed features of the drug." [Impax Br., D.I. 140 at 10-11]. But these requests are all specifically directed toward marketing documents comparing Effexor XR and ODV succinate. [*Id.* at 4-5]. In fact, Request No. 128 seeks "marketing plans for DESVENLAFAXINE . . . . " [*Id.* at 4]. Such documents, relating to a product that Wyeth has not yet marketed and which is not involved in this suit, are not relevant to the commercial success of the invention claimed by the patents-in-suit. Future marketing plans for a product yet to be launched have no relevance to the past ten years of Effexor XR's performance in the market. And that performance alone is enough to establish the commercial success of Effexor XR.

Impax argues that Wyeth's "strategies to transition the market to [ODV succinate] likely address Effexor XR®'s selling strengths and weaknesses . . . ." [Impax Br., D.I. 140 at 10]. Yet this is the kind of speculative theory of relevance which the Federal Rules do not permit. *See Micro Motion*, 894 F.2d at 1327-28 ("A litigant may not engage in merely speculative inquiries in the guise of relevant discovery.").

Furthermore, Wyeth has produced to Impax a large volume of marketing materials for Effexor XR which actually address Effexor XR's purported "selling strengths and weaknesses." Impax has not demonstrated that plans to market a future product for a different drug contain relevant information that would justify the enormous burden on Wyeth to collect, review, and produce such documents.

4. ODV Succinate Itself Is Not Relevant To The Claims And/Or Defenses In This Suit

Impax argues that ODV succinate clinical data is itself discoverable under the Federal Rules "because [ODV succinate] is the only major active metabolite of venlafaxine," and thus such data would therefore "show whether the Effexor XR product truly demonstrates an improvement in nausea and emesis." [Impax Br., D.I. 140 at 11-12]. But Impax does not explain how the pharmacological effect of the succinate salt of one of venlafaxine's metabolites bears on the question of whether the administration of extended release venlafaxine hydrochloride results in less nausea and emesis than the administration of immediate release venlafaxine hydrochloride. Whether desvenlafaxine is or is not an active metabolite or whether it has or does not have similar pharmacological activity to venlafaxine is simply irrelevant. The patents-in-suit do not discuss desvenlafaxine or ODV succinate, nor do the claims require the diminished incidences of nausea and emesis to be mediated by any of the metabolites of venlafaxine. ODV succinate is not relevant to any of the claims and/or defenses in this case.

5. Impax's Requests Are Overly Burdensome

Impax's Document Requests, some of which are facially "limited" to documents pertaining to comparisons of Effexor XR and ODV succinate, would require Wyeth to locate, review, and redact a massive amount of information that has been generated in connection with the research and development of an entirely new drug, ODV succinate. Indeed, the research and

development of this future product is of the same scope and magnitude as that of Effexor XR, and involved a large number of people in a variety of disciplines who might have responsive documents. Indeed, the document production pertaining to Effexor XR, which was largely conducted during the prior *Wyeth v. Teva* litigation, took over a year to complete. Compliance with Impax's Document Requests would require a significant amount of time, effort, and resources.

An article that Impax cites (Exhibit B to Impax's Brief, "Companies Desperately Seek Antidepressant Breakthrough") highlights the unreasonable scope of Impax's Document Requests. The article generally discusses the lengthy and uncertain nature of clinical trials on drugs to treat depression:

> Of the dozens of medications in development to treat anxiety and/or depression, only a few are in the mid- to late stages of development (phase 2 or phase 3 clinical trials). In these stages, medications are being tested in large-scale human clinical trials. Phase 2 involves testing a drug in 100 to 500 patients to evaluate the drug's effectiveness and identify side effects. Phase 3 involves testing a drug in 1,000 to 5,000 patients to confirm the drug's effectiveness and monitor adverse drug reactions over longer periods of time. By the time a drug reaches phase 3, it has already undergone years of scrutiny in the laboratory, animal trials, and smaller human trials and has the best chance of reaching pharmacy shelves within the next 18 months to three years.

[Matterer Decl., Ex. B at 2]. ODV succinate is identified in the article as one of the potential new drugs in mid- to late development that might be available in the next two to three years. [*Id.* at 3]. The lengthy and extensive phase 2 and phase 3 clinical trials, referred to in the article, which the FDA requires to prove the safety and efficacy of new drugs, such as ODV succinate, are but examples of the types of documents Impax would have Wyeth collect and review for possible production. Yet that collection and review would result in documents having nothing to do with any issue in this lawsuit. **REDACTED**

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V. CONCLUSION

For the reasons discussed above, Wyeth respectfully requests that the Court deny Impax's Motion to Compel Production of Documents in Response to Defendant's Fourth Set of Requests For Production (Nos. 125-131).

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April 24, 2007
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EXHIBIT A

REDACTED

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EXHIBIT B

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CERTIFICATE OF SERVICE

I, the undersigned, hereby certify that on May 2, 2007, I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing(s) to the following:

Mary B. Matterer
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I also certify that copies were caused to be served on May 2, 2007 upon the following in the manner indicated:

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